

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024						Introduction Type:	New Item		x Final Version			Date:	12/23	/2024
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharma	ceuticals, Inc.				Application:	ANDA	a. Temperature	e - Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 204316				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	le:								· -					
DUNS:	11-856-3719								Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Quetiapi	ine Tablets, USP 300 mg						(write in)					
Selling Unit NDC:	31722-768-01		Unit of Use NDC:				722768016		Notes					
UDI			CVX Code:			MVX Code:		l						
Description:	Quetiapine Table	ts, USP 300 mg							Is this product to be shipped	I to customers on ic	e?		No	
									Is this product to be shipped	I to customers on d	ry ice?		No	
Active Ingredient(s):		Quetiapine fumarate,	USP											
UBL for Additional Bondon Information									temperature excursion que	estions:	Soma Raju			
URL for Additional Product Inform Address:	ation: 800 Centennial A	www.camberpharma.c	com			Address 2:		8 1	Name: Number:		732-529-042	2		
City:	Piscataway	ive, Juile 1			State:		: 08854		Group E-mail:				<u> </u>	
Key Contact:	Customer Service					customerservice@cam		Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regu	ulations for product in any	states?			No	
Product Therapeutic Classification):	Atypical antipsychotic	:						Special returns requirement				No	
•										·				
	ADDIT	IONAL PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	300 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		NI.				Dosage Form:	Film-coated tablet		Unit of Sale		What is the	NDC selling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present					ll r	x Bottle		1 Bottle of 10		umr	
latex-free?		Yes					Capsule, biconvex		Box/Carton			g. 1 Box of 10	(Vials)	
preservative-free?		Yes	Dairy, Lactose, A	Animal Product	s	Product Shape:	Capcale, Bicerrox		Ampule		(**************************************	g. 1 Box 01 10	· · · · · · · · · · · · · · · · · · ·	
correctional institution block?		No				Product Color:	White		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with '45' on one side and 'I' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						and 1 on the other side		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un Trade Agreements Act (T.		No				Vial Powder Sgl Vial Powder Multi			Each	DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1)	AA)?	NO			-	Other: Write In			Inner/Carton Case	Раск	
			FOR GENERIC DRUG PRO	DUCTE				l.	Other. Write iii			Case		
			FOR GENERIC DRUG FRO	00013										
					Au	thorized Generic *If A	uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB	Authorized Generic in Authorized Generic in Authorized Generic, other section fields are not applicat						Rec. sell unit to customer? Rx billing unit to pharmacy				.01/1		
II. Generic Equivalent to What Bran								itee. sen unit t					cy.	
in conone Equivalent to Tinat Erai	nd?·	Seroquel								1		Fach		
	nd?:	Seroquel						(Write-in, e.g. 1				Each Gram		
	nd?:		CHAIN SECURITY ACT (E	OSCSA) INFORM	MATION			(Write-in, e.g. '	1 Vial)					
		DRUG SUPPLY	<u> </u>	_					1 Vial) e:			Gram Milliliter		
Does supplier meet DSCSA definit		DRUG SUPPLY	Yes		MATION GLN:				1 Vial) e:	AND PACKING IN		Gram Milliliter		
Does supplier meet DSCSA definit Is product exempt from DSCSA?		DRUG SUPPLY	<u> </u>						1 Vial) e:		IFORMATION	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption:		DRUG SUPPLY	Yes						1 Vial) e: ITEN	Dimensio	IFORMATION	Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:		DRUG SUPPLY	Yes No		GLN: GCP:			HCPCS J-Code	1 Vial) e:		IFORMATION	Gram Milliliter	Volume (Cube)	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	ion of manufactu	DRUG SUPPLY	Yes No		GLN: GCP: If yes, was or	iginal product purchase	d		1 Vial) e: ITEN	Dimensio	IFORMATION	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	ion of manufactu	DRUG SUPPLY	Yes No No Yes		GLN: GCP: If yes, was or direct from m	fr?		HCPCS J-Code	1 Vial) e: ITEM Weight Lbs. 0.26	Dimensio Depth	DONE (US msm Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	ion of manufactu exclusive distrib Vexemption for p	DRUG SUPPLY	Yes No		GLN: GCP: If yes, was or direct from m			HCPCS J-Code Item/Each: Box/Carton/Bu	1 Vial) e: ITEM Weight Lbs. 0.26	Dimensio Depth	DONE (US msm Width	Gram Milliliter	(Cube)	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation fron Saleable Unit of Measure X	exclusive distrib v/exemption for p n FDA. RFID tag(Y/N) N	DRUG SUPPLY rer? utor? roduct? GTIN Saleable Quantity 1 24	Yes No No Yes No AND HIBCC PRODUCT IN HIBCC	FORMATION	GLN: GCP: If yes, was or direct from m Provide source GTII 0033	hr? be manufacturer for rep: N-14 31722768016 31722768010 rd letter, PACKAGE INSE	ackaged product	Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet: Regular Cost (National Cost (1 Vial) e: Weight Lbs. 0.26 undle/ 6.95 COST INFORMATION WAC) (\$) 3/18/2024	Dimensic Depth 2.19	Use of the second of the secon	Gram Milliliter I Height 3.88	(Cube) 18.61 655.59	Pieces 1 24



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Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	ii yes, indicate which.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group	Tidzurdous Trasic lastinisation						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
, ,	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS						
	Is there a REMS on this product?						
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?	Website UKL.						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	Comments						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No							
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No							
	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only: No	INU						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:						



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?